DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

M-2253D

PURGED FH

December 8, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 06

Robert M. Kaminski
Chief Executive Officer
Leiner Health Products Inc.
901 East 233rd Street
Carson, California 90745

Dear Mr. Kaminski:

During our recent inspection of your Leiner Health Products repacking operation, located in Madison, WI, our investigator found serious violations of the current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your repacked prescription drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The violations observed during our inspection include but are not limited to the following:

1. Failure of your batch production and control records to include complete information relating to the production and control of each batch (21 CFR 211.188). For example, unlabeled bottles of ∿∿∿ from line #2 were being torque tested on line #3 and left there unlabeled. At least one of these was not opened and inspected to confirm its contents (per SOP M 35-10-8A, Unlabeled Bottle Procedure), all were not turned over to the

pharmacist supervisor for an investigation, and the incident was not investigated and documented at the time.

2. Failure to appropriately investigate related batches once the drug product was returned (21 CFR 211.204). For example, the follow-up investigation concerning the ~~~~~ mix-up is incomplete. There is no documentation to show that a determination was made as to how long the torque tester on line #2 was inoperable and if any other lots of product bottled and labeled during the time period could have resulted in the same problem.

3. Failure to clean equipment at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product [21 CFR 211.67(a)], and failure to establish written procedures [21 CFR 211.67(b)]. For example, no protocol has been developed for your cleaning validation and only preliminary baseline testing has been conducted.

4. Failure to determine equipment used in the manufacture, processing, packing, and holding of a drug product performs the desired function satisfactorily [21 CFR 211.68(a)]. For example, no installation qualification or operational qualification has been performed on lines #2 and #3 and no production qualification has been performed on any of your lines.

5. Failure to ensure that each person engaged in the manufacture, processing, packing, or holding of a drug product has the education, training, and experience to enable that person to perform the assigned function [21 CFR 211.25. For example, employee ~~ has not been trained at a minimum twice a year in the GMPs per your SOP M 07-02-1A.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that FDA expects all your locations to be in compliance.

Your response, dated November 25, 1998, to the form FDA-483 issued to your firm on November 9, 1998, appears to be satisfactory with the exception of your response to observation #3 concerning the cleaning validation and packaging validation. We appreciate that your firm's current decision is [illegible] However, [illegible] and is subject to the laws and regulations of the Act. We also appreciate that you are working [illegible] Please be aware that the lines must be validated before your repackaging operation [illegible] Promised corrections will be verified during our next inspection. Your response will be made part of the official file for your firm.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl

xc: Thomas G. Hungerford
QA Manager
Leiner Health Products Inc.
2300 Badger Lane
Madison, WI 53713